

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING I | DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. 7252 | |
|-----------------------|------------|----------------------------|----------------------|---------------------|-----------------------|--|
| 10/661,780 | 09/15/2 | 2003 | Philippe Bouchard | 098501-0305998 | | |
| 909 | 7590 | 12/16/2005 | | EXAMINER | | |
| | RY WINTHRO | DELACROIX MUIRHEI, CYBILLE | | | | |
| P.O. BOX : MCLEAN, | VA 22102 | | ART UNIT | PAPER NUMBER | | |
| • | | | | 1614 | - | |

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Applic | ation No. | Applicant(s) | Applicant(s) | | | | |
|---|--|--|--|--|--------------|--|--|--|--|
| Office Action Summary | | | 1,780 | BOUCHARD ET | TAL. | | | | |
| | | | ner | Art Unit | | | | | |
| | | 1 - | Delacroix-Muirheid | • | | | | | |
| Period fo | The MAILING DATE of this communica or Reply | tion appears on | the cover sheet w | ith the correspondence | address | | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL asions of time may be available under the provisions of 3 SIX (6) MONTHS from the mailing date of this communic period for reply is specified above, the maximum statum to reply within the set or extended period for reply will, reply received by the Office later than three months after ad patent term adjustment. See 37 CFR 1.704(b). | LING DATE OF 17 CFR 1.136(a). In no cation. ory period will apply an by statute, cause the | THIS COMMUNIO be event, however, may a red and will expire SIX (6) MON application to become AB | CATION. reply be timely filed ITHS from the mailing date of this BANDONED (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed of | on 27 Sentembe | er 2005 | | | | | | |
| · — | | ☐ This action i | | | | | | | |
| | Since this application is in condition for | | | ters, prosecution as to t | he merits is | | | | |
| ,,_ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Dispositi | on of Claims | · | • , | | | | | | |
| 4)⊠ Claim(s) <u>22,26-34 and 36-42</u> is/are pending in the application. | | | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | | | | |
| · | 6)⊠ Claim(s) <u>22,26-34 and 36-42</u> is/are rejected. | | | | | | | | |
| | 7) Claim(s) is/are objected to. | | | | | | | | |
| 8) | Claim(s) are subject to restriction | n and/or electio | n requirement. | | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9)□ | The specification is objected to by the E | vaminer | | | | | | | |
| · — | The drawing(s) filed on is/are: a) | | b)□ objected to | by the Examiner | | | | | |
| , | Applicant may not request that any objectio | • | • | • | • | | | | |
| | Replacement drawing sheet(s) including the | | | • • | | | | | |
| 11) | The oath or declaration is objected to by | | · - | • • | • • | | | | |
| Priority u | inder 35 U.S.C. § 119 | | | | | | | | |
| | Acknowledgment is made of a claim for ☐ All b)☐ Some * c)☐ None of: | foreign priority | under 35 U.S.C. § | 3 119(a)-(d) or (f). | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | | |
| | application from the International | Bureau (PCT F | Rule 17.2(a)). | | | | | | |
| * S | ee the attached detailed Office action for | or a list of the ce | ertified copies not | received. | | | | | |
| | | | | | | | | | |
| Attachment | • • | | _ | | • | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO- | 040) | | Summary (PTO-413) s)/Mail Date | | | | | |
| 3) 🔲 Inform | e or Draftsperson's Patent Drawing Review (PTO- nation Disclosure Statement(s) (PTO-1449 or PTO · No(s)/Mail Date | | | nformal Patent Application (P | TO-152) | | | | |

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Detailed Action

The following is responsive to applicant's amendment received Sep. 27, 2005.

Claims 1-21, 23-25, 35 are cancelled. No new claims are added. Claims 22, 26-34, 36-42 are currently pending.

The previous objection to claims 31 and 36 set forth in paragraph 1 of the office action mailed March 28, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, second paragraph, set forth in paragraphs 2-5 of the office action mailed March 28, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(a) over Olivennes et al., set forth in paragraph 6 of the office action mailed March 28, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) over Olivennes et al., set forth in paragraph 7 of the office action mailed March 28, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's amendment necessitates the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Objection(s)

Claim 39 is objected to because of the following informalities: in line 4, "administrating" should read –administering--. Appropriate correction is required.

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Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 26-34, 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "the improvement" in line 5. There is insufficient antecedent basis for this limitation in the claim. If claim 22 is to be a Jepson claim, the proper Jepson claim format should be used.

Claim 26 recites the limitation "clomphencitrate" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 22, 26-34, 36-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See In re Berg, 140 F.3d 1428. 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in the claims 1-6 of USPN '192. That is, the claims of USPN '192 fall entirely within the scope of the claims of the instant application. In other words, the claims of the instant application are anticipated by claims 1-6 of USPN '192. Specifically, the claims of USPN '192 recite a method of therapeutic management of infertility comprising administering an LH-RH antagonist, stimulating ovarian follicle growth, inducing ovulation with HCG, native LHRH, LHRH agonist or recombinant LH and inseminating by sperm injection, wherein the LHRH antagonist administered may be cetrorelix or antarelix and ovarian follicle stimulation is achieved by administration of anti-estrogens. Since, the claims of USPN '192 administer the LHRH antagonist so that endogenous LH is suppressed, maintaining FSH secretion at a natural level without effecting estrogen development would be inherent.

Conclusion

Claims 22, 26-34, 36-42 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM (1) V Dec. 12, 2005

> CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600